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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,117	12/30/2003	David M. Gravett	110129.434	3276
41551	7590	07/26/2006	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVENYUE, SUITE 6300 SEATTLE, WA 98104-7092			ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER

1618

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/749,117	Applicant(s) GRAVETT ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10, 13, 14, 17-21, 75, 84-99, 102 and 105-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 13, 14, 17-21, 75, 84-99, 102 and 105-112 is/are rejected.
- 7) ☒ Claim(s) 1, 89, 93 and 110 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/30/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 06/19/2006 is acknowledged. Applicant's election of species is also acknowledged. Applicant submitted that the following claims read upon the elected features: claims 1-7, 10, 13-14, 17-21, 75-84, 87-99, 102 and 105-112. The examiner disagrees with the following claims being readable upon the elected features: claim 7 which reads that the PAO polymers are PEG, the elected genus PAO does not read on the species PEG; claims 76-83 read on a drug that further comprises a polymer, applicants elected the specific drug paclitaxel which does not support a drug comprising a polymer since paclitaxel is an organic molecule and does not reasonably comprise a polymer. Regarding claims 13, 14, 17-20 and 105 which all have limitations on the type of drug, it was assumed by the examiner that since the applicants elected the specific species paclitaxel it would meet all of the limitations for the drug in the above claims even though it is a species and the above claims seem to deal with a broader genus of different drugs. Claims 85 and 86 are searchable. Therefore the examiner will search the following claims, which are searchable from group I and the elected species: 1-6, 10, 13-14, 17-21, 75, 84-99, 102 and 105-112.

Claim Objections

Claims 1, 89, 93 and 110 are objected to because of the following informalities: there is a typo in all the claims for $m \geq 2$ and $n \geq 2$ the spacing is too narrow the \geq is typed over the 2 in each instance. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,89,92,93 and 110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All the above claims read on a first component given by the formula Compound₁-(SH)_m and a second component given by the formula Compound₂-Y_n. While the examiner understands that the two compounds are a core and can contain multiple bonds to either nucleophilic or electrophilic groups, this is not clearly stated in the claims, instead, from how it is written, it is not clear that the functional groups are only attached to the core and not to themselves for instance. It is suggested by the examiner that the applicants change the wording of Compound to core so the claims are more definitive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,10,75, 84-99,102 and 105-112 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al. (US 6,312,725).

Wallace teaches rapid gelling (<1 min) biocompatible polymer compositions that can be used for *in vivo* administration that are comprised of two components, the first is

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a nucleophilic PAO containing 4-12 sulfhydryl nucleophilic groups and the second is an electrophilic PAO which can contain a mixture of between 4-12 succinimidyl and maleimidyl electrophilic groups, the composition can further contain optional materials such as drugs, antibiotics and methylated collagen. See abstr, col 1 lin 66-col 2 lin 60, col 4 lin 8-67, col 5 lin 9-col 6 lin 8, col 8 lin 9-23, col 10 lin 55-col 11 lin 2, examples and claims. Wallace also teaches that the nucleophilic polymer can be contained in an alkaline buffer solution of sodium phosphate/carbonate within the pH range specified by applicants and the electrophilic polymer can be contained in an acidic buffer solution. See col 9 lin 12-45 and examples. Each component of the composition is administered separately to the tissue site or both together, then within a short time after being mixed together at the site of administration the composition forms a gel, this statement in the Wallace patent meets the limitations in claim 89 that the first and second component are administered sequentially or subsequently, the drug is contained within the PAO gel. See col 3 lin 25-32 and examples.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6,10,13-14,17-21,75, 84-99,102 and 105-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (US 6,312,725) in view of Loomis (US 5,854,382).

Wallace is disclosed above. Wallace while disclosing that the gels can comprise drugs the patent is silent on specific drugs such as paclitaxel.

Loomis is used to primarily show that the use of paclitaxel in biocompatible crosslinked PAO gels was well known in the art at the time of invention. See abstr, col 5 lin 36-51, col 7 lin 10-16.

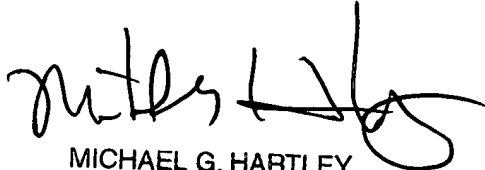
It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Wallace discloses all that is claimed within applicants current application but is silent on the use of the exact drug paclitaxel while the Loomis patent discloses that it was well known in the art to use paclitaxel in biocompatible crosslinked PAO gels. The motivation to combine the above documents would be the formation of a rapid gelling biocompatible polymer composition comprising anti-tumor agents such as paclitaxel. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER